UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

MASHON BAINES and NANCIE FRONING on behalf of themselves and all others similarly situated, **Plaintiffs,** **v.** **NATURE'S BOUNTY (NY), INC. and THE BOUNTIFUL COMPANY (NY)** **Defendants.**	**Case No. 2:21-cv-05330-JS-AYS** **Class Action** **COMPLAINT FOR DAMAGES, EQUITABLE, DECLARATORY, AND INJUNCTIVE RELIEF** **DEMAND FOR JURY TRIAL**

Plaintiffs Mashon Baines and Nancie Froning ("Plaintiffs"), on behalf of themselves and all others similarly situated, bring this class action against The Bountiful Company and its subsidiary Nature's Bounty Inc (collectively "NBI" or "Defendants"), and on the basis of personal knowledge, information and belief, and the investigation of counsel, allege as follows:

INTRODUCTION

1. This is a proposed class action on behalf of a nationwide, New York and California classes of consumers seeking redress for Defendants' deceptive practices associated with the advertising, labeling and sale of its Nature's Bounty 1400 mg Fish Oil. ("Product" or "Supplement").

2. Fish is a major source of healthful long-chain omega-3 fats and are rich in nutrients such as vitamin D and selenium, high in protein, and low in saturated fat. Numerous studies have shown that consuming fatty fish 2-3 times a week reduces the risk of heart disease and stroke, as well as provides a myriad of additional health benefits.

3. Unfortunately, most Americans do not, or cannot, consume fatty fish with such regularity and have instead turned to the consumption of fish oil.

4. Indeed, by 2012, fish oil supplements had become the most commonly used non-vitamin, non-mineral dietary supplement sold in the U.S., and to this day remain one of the most popular dietary supplement offerings. By 2019, the global fish oil market was valued at $1.9 billion, and is estimated to reach $2.8 billion by 2027. It remains a lucrative business with numerous market participants vying for consumer attention and their spending dollars.

5. Defendants manufacture, label and sell a Product which they claim to be 1400 mg of Fish Oil containing of 647 mg of Eicosapentaenoic Acid ("EPA") and 253 mg of Docosahexaenoic Acid ("DHA")—the essential omega-3 fatty acids that naturally occur in fish.[1]

Supplement Facts

Serving Size 1 Softgel

Amount Per Serving		%Daily Value
Calories	15	
Total Fat	1.5 g	2%**
Polyunsaturated Fat	1.5 g	***
Cholesterol	5 mg	2%
Fish Oil	1,400 mg (1.4 g)	***
provides 980 mg of Total Omega-3 Fatty Acids† comprising of:		***
EPA (Eicosapentaenoic Acid)	647 mg	***
DHA (Docosahexaenoic Acid)	253 mg	***
Other Omega-3 Fatty Acids		***

**Percent Daily Values are based on a 2,000 calorie diet.
***Daily Value not established.

6. They also proudly claim that the contents are USP verified, which, among other things, assures consumers that the Product "contains the ingredients listed on the label, in the declared potency and amounts."[2]

7. Contrary to what is represented on the label, however, this Product is not fish oil, nor does it contain a single milligram of EPA or DHA.

8. What was once a low-grade oil derived from fish offal, has been subjected to a chemical process by which its molecular structure and constituent parts have been substantially

[1] Class Products include: Nature's Bounty 1400 mg Fish Oil, Nature's Bounty 2400 mg Fish Oil, and Nature's Bounty 1290 mg Mini Fish Oil products.

[2] https://www.usp.org/verification-services/verified-mark.

transformed and irrevocably altered into a synthesized product that does not otherwise exist in fish, or nature. Through this chemical process, known as trans-esterification, an industrial solvent is introduced into the fish oil in order to break its natural triglyceride bonds and cleave the glycerol backbone from fatty acid molecules. Thereafter, ethanol is introduced to which the newly freed fatty acids bond to form fatty acid ethyl esters. Fish oil is stripped of hundreds of its constituent sub ingredients, and the Omega-3s, which include DHA and EPA, are converted into ethyl esters. Critically, these newly formed Omega-3s are different molecules than the Omega-3s which exist naturally in fish oil. These new chemical by-products are universally recognized by their common or usual name—Fatty Acid Ethyl Esters ("FAEE").

9. The most material representation on a dietary supplement label is its statement of identity, or common name, as it provides consumers with a basic understanding of the Product's contents.

10. Once trans-esterified, fish oil is irrevocably transformed into a FAEE. It is no longer fish oil and cannot be so named or labeled. To do so, as NBI has done, is false, misleading, deceptive, unlawful, and perpetrates an actionable fraud on the consuming public.

11. As alleged herein, Defendants' conduct is in breach of warranty, violates N.Y. Gen. Bus. Law §§ 349 *et seq.*, N.Y. Gen. Bus. Law §§ 350 *et seq.*, California's Business and Professions Code § 17200, *et. seq.,* California's Business & Professions Code § 17500, *et. seq.,* California Civil Code § 1750, *et seq*., and is otherwise grounds for restitution on the basis of quasi-contract/unjust enrichment.

12. Throughout the applicable class period, Defendants falsely represented the fundamental nature of their Product, and as a result of this false and misleading labeling, were

able to sell these Products to tens of thousands of unsuspecting consumers throughout New York, California and the United States.

JURISDICTION AND VENUE

13. Jurisdiction of this Court is proper under 28 U.S.C. § 1332(d)(2). Diversity jurisdiction exists as Plaintiff Baines is a resident of Rome, New York. Plaintiff Froning is a resident of San Diego, California. Defendant Nature's Bounty Inc. is a New York corporation with its principal place of business in Ronkonkoma, New York. The Bountiful Company is a Delaware Corporation, with its principal place of business in Ronkonkoma, New York. The amount in controversy exceeds $5,000,000 for the Plaintiffs and members of the Class collectively, exclusive of interest and costs, by virtue of the combined purchase prices paid by Plaintiffs and members of the putative Class, and the profits reaped by Defendants from their transactions with Plaintiffs and the Class, as a direct and proximate result of the wrongful conduct alleged herein, and by virtue of the injunctive and equitable relief sought.

14. Venue is proper within this judicial district pursuant to 28 U.S. C. § 1391 because a substantial portion of the underlying transactions and events complained of occurred and affected persons and entities are located in this judicial district. In addition, Defendants are headquartered here and make all relevant decisions in the District.

PARTIES

15. Plaintiff Mashon Baines is a resident of Rome, New York.

16. Ms. Baines is a purchaser of Defendants' 1400 mg Fish Oil. She purchased the Product on numerous occasions over the past 3 years, including a purchase in or around March 2021, from Price Chopper in Rome, New York.

17. Ms. Baines believed the representations on the Product's label that, among other things, it was actual fish oil containing DHA and EPA.

18. Ms. Baines believed that Defendants lawfully marketed and sold the Product.

19. Ms. Baines relied on Defendants' labeling and was misled thereby.

20. Ms. Baines would not have purchased the Product, or would have purchased the Product on different terms, had she known the truth.

21. Ms. Baines was injured in fact and lost money as a result of Defendants' improper conduct.

22. If Ms. Baines knew that Defendants' marketing and sale of the Product was lawful, and not misleading, and/or that she could rely on the labeling claims, she would purchase and/or would consider purchasing the Product in the future. At present, however, and without an injunction, Plaintiff cannot purchase the Product because she cannot be confident that its labeling is not misleading.

23. If Ms. Baines in the future believes that Defendants' marketing and labeling is not misleading and lawful, she would consider purchasing the Product in the future.

24. Plaintiff Nancie Froning is a resident of San Diego, California.

25. Ms. Froning is a purchaser of Defendants' 1400 mg Fish Oil. She has purchased the Product on numerous occasions over the past 3 years from several stores, including but not limited to, CVS and Walmart. Her latest purchase was in August or September of 2021.

26. Ms. Froning believed the representations on the Product's label that, among other things, it was actual fish oil containing DHA and EPA.

27. Ms. Froning believed that Defendants lawfully marketed and sold the Product.

28. Ms. Froning relied on Defendants' labeling and was misled thereby.

29. Ms. Froning would not have purchased the Product, or would have purchased the Product on different terms, had she known the truth.

30. Ms. Froning was injured in fact and lost money as a result of Defendants' improper conduct.

31. If Ms. Froning knew that Defendants' marketing and sale of the Product was lawful, and not misleading, and/or that she could rely on the labeling claims, she would purchase and/or would consider purchasing the Product in the future. At present, however, and without an injunction, Plaintiff cannot purchase the Product because she cannot be confident that its labeling is not misleading.

32. If Ms. Froning in the future believes that Defendants' marketing and labeling is not misleading, and lawful, she would consider purchasing the Product in the future.

33. Defendant Nature's Bounty Inc., is a New York Corporation with its principal place of business in Ronkonkoma, New York. Nature's Bounty is the flagship brand of The Bountiful Company, a family of wellness brands "committed to providing people with high

quality products to complement their lifestyles and physical health."[3] NBI sells a variety of vitamins and supplements including the Product at issue in this litigation.

34. Defendant The Bountiful Company ("TBC") is a Delaware Corporation with its principal place of business in Ronkonkoma, New York. TBC is a manufacturer, marketer and seller of vitamins, minerals, herbal and other specialty supplements. It owns several vitamin/supplement brands including Defendant Nature's Bounty.

35. In August 2021, Nestle Health Science completed its acquisition of The Bountiful Company and its subsidiaries including NBI, for $5.75 billion.

GENERAL ALLEGATIONS

A. Omega-3 Fatty Acids

36. Omega-3 Fatty Acids ("Omega-3" or "OM3") are polyunsaturated carboxylic acids that provide numerous health benefits to the human body including a variety of critical organs and systems (*e.g.*, heart, brain, eyes, blood vessels, lungs, immune, endocrine, and reproductive systems).[4]

[3] https://www.naturesbounty.com/about-us/

[4] *Omega-3 Fatty Acids*, National Institutes of Health, Office of Dietary Supplements, available at https://ods.od.nih.gov/factsheets/Omega3FattyAcids-Consumer; H. Breivik, *Long-chain Omega-3 Specialty Oils*, Woodhead Publishing in Food Science, Technology and Nutrition at 11 (hereinafter "Breivik at ___") (Clinical research has suggested that Omega-3s help prevent cardiovascular disease, Alzheimer's, dementia, macular degeneration, and rheumatoid arthritis. There is also support that Omega-3s provide benefits for sufferers of arthritis, Crohn's disease and patients with neuropsychiatric disorders such as depression and schizophrenia).

37. Among the 11 types of OM3s, the three most important to human physiology are alpha-linolenic acid ("ALA"), docosahexaenoic acid ("DHA") and eicosapentaenoic acid ("EPA").[5]

38. ALA Omega-3 fatty acids are primarily found in plant oils and generally used by the human body for energy. To be used for something other than energy, ALA must first be converted into EPA or DHA. Unfortunately, this conversion process is inefficient and results in only a small percentage of ALA being converted into EPA and DHA.

39. In contrast, the primary source of EPA and DHA are marine oils from fatty fish and other seafoods.

40. Although experts have not established a daily recommended amount for DHA and EPA, the National Institutes of Health, Office of Dietary Supplements ("NIH") acknowledges that many scientific studies show that eating fatty fish rich in DHA and EPA has beneficial effects with respect to a variety of adverse health conditions such as cardiovascular disease, age-related macular degeneration, Alzheimer's disease, dementia, dwindling cognitive function, rheumatoid arthritis, high blood pressure, and variety of other conditions including, potentially, certain cancers.[6]

41. Between 2017 and 2019, the American Heart Association ("AHA") released three science advisories related to Omega-3s, all of which recommend adults consume one to two servings of seafood per week to reduce the risk of congestive heart failure, coronary artery

[5] Other Omega-3s include: hexadecatrienoic acid (HTA); stearidonic acid (SDA); eicosatrienoic acid (ETE); eicosatetraenoic acid (ETA); heneicosapentaenoic acid (HPA); docosapentaenoic acid (DPA); tetracosapentaenoic acid; and tetracosahexaenoic acid.

[6] Available at https://ods.od.nih.gov/factsheets/Omega3FattyAcids-Consumer/

disease, stroke, and sudden cardiac death. For people with existing coronary artery disease, the AHA recommends approximately 1 g./day of EPA plus DHA, preferably from oily fish.[7]

42. In 2019 the U.S. Food and Drug Administration ("FDA") considered the weight of scientific evidence on the impact of OM3 and approved five qualified health claims relating to the consumption of the EPA/DHA and its effect on heart health.[8]

43. Unfortunately, Americans generally do not consume a sufficient amount of fatty fish necessary to maintain adequate levels of EPA and DHA. In response to this deficiency, health care professionals began recommending that Americans supplement their diets with fish oil.[9]

44. In 1995, fish oil supplements generated only $35 million in annual sales. By 2005, that number had increased to $310 million and by 2012, fish oil supplements had become the non-vitamin/non-mineral natural product most commonly taken by both adults and children with approximately 7.8 percent of adults (18.8 million) and 1.1 percent of children age 4 to 17

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[7] Etherton, P., et al, *Omega-3 Fatty Acids and Cardiovascular Disease New Recommendations From the American Heart Association*, AHA Arteriosclerosis, Thrombosis, and Vascular Biology Journal (2003) available at https://www.ahajournals.org/doi/full/10.1161/01.ATV.0000057393.97337.AE; *See also*, National Institutes of Health, *Omega-3 Fatty Acids*, available at https://ods.od.nih.gov/factsheets/Omega3FattyAcids-HealthProfessional/#:~:text=For%20people%20with%20existing%20coronary,of%20a%20physician%20%5B80%5D.

[8] *FDA Announces New Qualified Health Claims for EPA and DHA Omega-3 Consumption and the Risk of Hypertension and Coronary Heart Disease*, June 19, 2019, available at https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-new-qualified-health-claims-epa-and-dha-omega-3-consumption-and-risk-hypertension-and.

[9] Mackay, *A Comparison of Synthetic Ethyl Ester Form Fish Oil vs. Natural Triglyceride Form*, available from http://www.promedics.ca/site/downloads/Triglycerides%20vs%20Ethyl%20Esters.pdf.

(664,000) regularly consuming fish oil supplements.[10] By 2019, the global fish oil market had grown to $1.9 billion, and is currently estimated to reach $2.8 billion by 2027.[11]

B. Fish Oil

45. Omega-3 fatty acids, including EPA and DHA, are found in a variety of fatty fish such menhaden, sardines, anchovies, salmon and tuna.[12] The oil from these fish is extracted by a fairly straightforward process which has been employed in a similar fashion since the early 1800s whereby fish were caught, cooked and a rock weighted process was used to press oil from the fish. By the 1850s, the rock weighted process was replaced with a hydraulic press.[13]

46. Today, the process remains relatively the same. Once fish are caught, they are on-boarded to a fishing vessel and quickly boiled. The fish are cooked and pressed, separating the water and oil from proteins and solids. Thereafter, the water is separated from the oil. The oil undergoes a polishing process (*i.e.*, deacidifying, degumming, and washing the oil several times).

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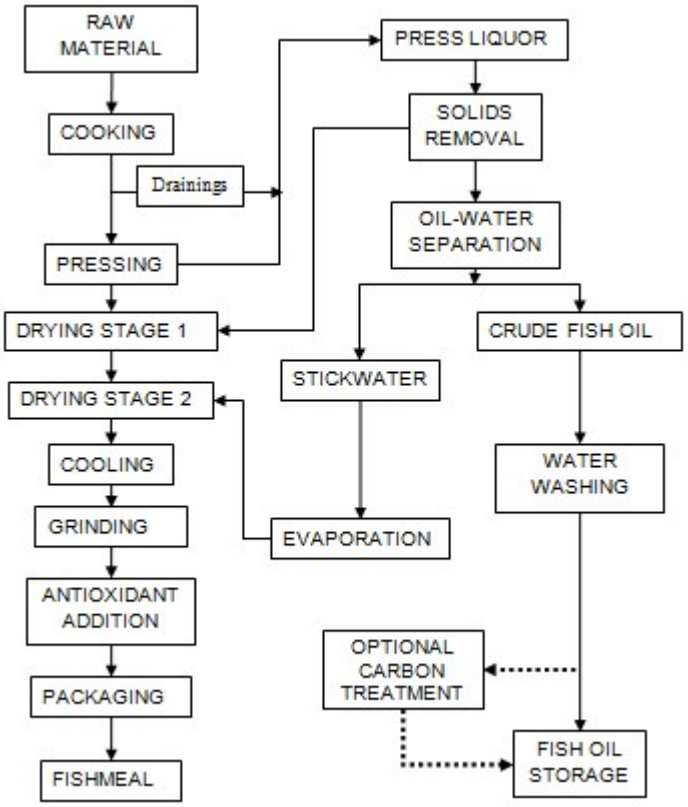
[10] NIH, *Omega-3 Supplements: In Depth*, National Center for Complementary and Integrative Health, available at https://www.nccih.nih.gov/health/omega3-supplements-in-depth#:~:text=Use%20of%20Omega%2D3%20Supplements%20in%20the%20United%20States&text=The%20survey%20findings%20indicated%20that,in%20the%20previous%2030%20days.

[11] Global Fish Oil Market (2020 to 2027) - Opportunity Analysis and Industry Forecast - ResearchAndMarkets.com, Business Wire, available at https://www.businesswire.com/news/home/20200909005847/en/Global-Fish-Oil-Market-2020-to-2027---Opportunity-Analysis-and-Industry-Forecast---ResearchAndMarkets.com#:~:text=The%20global%20fish%20oil%20market,and%20docosahexaenoic%20acids%20 (DHA).

[12] Hossain, M.A., *Fish as Source of Polyunsaturated Fatty Acids (PUFAs), Which One is Better-Farmed or Wild?*, Advance Journal of Food Science and Technology 3(6): 455, 459 (Table 2), 2011 ("Hossain Publication").

[13] Breivik at 28.

It is subsequently bleached and deodorized. The resulting oil is ultimately encapsulated and sold as supplements. Below, a diagram representing the standard method for processing fish oil.[14]



47. Most significantly, common fish oil is ***derived using a physical, rather than a chemical process***, such that no chemical bonds are broken or created during the extraction, bleaching or deodorizing process. "Fish oil is produced without solvent extraction [but rather] is pressed out of the cooked fish."[15]

[14] Bimbo, A. (2011). *Marine oils; edible oil processing*. AOCS Lipid Library, December 2016, available at https://lipidlibrary.aocs.org/edible-oil-processing/marine-oils. The graph represents the wet reduction process—the most common method used to convert raw fish into fish oil.

[15] Breivik at 25.

48. The Omega-3 fatty acids in fish oil occur naturally in triglyceride form ("TAG"). Triglyceride is the term used to define the molecular structure which bond these fatty acids (i.e., EPA and DHA) to a glycerol backbone. Triglycerides are the natural molecular form that make up virtually all fats and oils in both animals and plants and which the human body can directly digest.[16]

49. Depending on the type of fish from which oil was derived, and the environmental conditions in which that fish was raised, the ratio of EPA and DHA can differ slightly, but typically will account for 30% of the fatty acid content (*i.e.*, 180 mg of EPA and 120 mg of DHA per 1000 mg of oil).[17] Standard fish oil therefore is often referred to as "18:12," representing the typical ratio of EPA to DHA by weight (18% of the oil by weight is EPA; and 12% of the oil by weight is DHA). The remaining 70% of the fish oil consists of saturated fats, other omega-3 fatty acids, omega-6 and omega-9 fatty acids.[18]

C. Omega-3 Fatty Acid Ethyl Esters

50. In the early 1980s, the Japanese pharmaceutical company Mochida developed a large-scale method to synthesize EPA and DHA into an ethyl ester chemical form. The process,

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[16] *See, e.g.,* Omega3 of Norway, available at https://norwayomega.com/omega3-fish-oil/#natural-triglycerides-vs-artificial-ethylesters (last visited April 14, 2021).

[17] NIH, *Omega-3 Fatty Acids, Fact Sheet for Health Professionals, National Institutes of Health, Office of Dietary Supplements ("NIH Fact Sheet")* available at https://ods.od.nih.gov/factsheets/Omega3FattyAcids-HealthProfessional.

[18] Lembke, P., *Production Techniques for Omega-3 Concentrates*, Omega-6/3 Fatty Acids: Functions, sustainability Strategy and Perspectives, DOI 10.1007/978-1-62703-215-5 (2013) available at https://www.puroomega.com/wp-content/uploads/2016/06/Lembke-2013-Production-Techniques-Omega-3-Human-Press-2013-pp353-364.pdf (last visited April 14, 2021).

known as trans-esterification, enabled scientists to increase the yield of omega-3s from 30% to upwards of 70% as well as manipulate the ratio between EPA and DHA ethyl esters.[19] It also allowed chemists to use low grade fish oil as the starting material as rancidity and other infirmities are removed in the trans-esterification process.

51. Doing so, however, required the chemical alteration of fish oil on a molecular level, substantially transforming it from a natural product, into a synthetic product called a Fatty Acid Ethyl Ester—a substance that is not found anywhere in nature, and which has not been comparably viewed by leading health authorities.

1. The Trans-Esterification Process

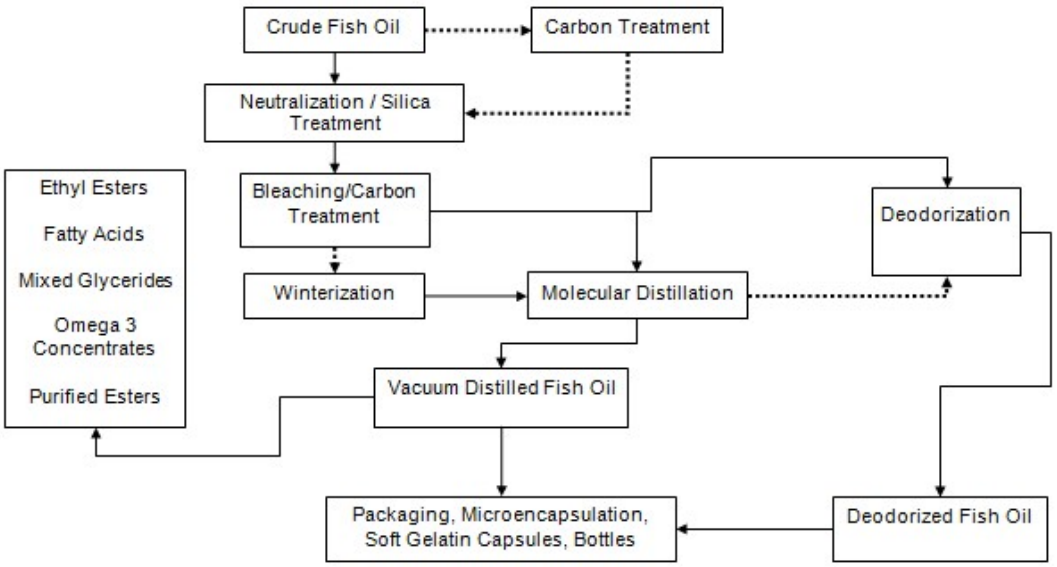
52. The first step in the trans-esterification process involves a chemical reaction whereby the glycerol backbone of each triglyceride molecule in the fish oil is broken by introduction of an industrial chemical such as sodium hydroxide, resulting in free fatty acids and a free glycerol molecule.[20] The free fatty acid forms of EPA and DHA, which are inherently unstable, are then chemically reacted with ethanol (an industrial alcohol).[21] In a subsequent process known as molecular distillation, the mixture is heat distilled under a vacuum resulting in

[19] Klinik, M., *A Review of Omega-3 Ethyl Esters for Cardiovascular Prevention and Treatment of Increased Blood Triglyceride Levels*, Vasc Health Risk Manag (2006), doi: 10.2147/vhrm.2006.2.3.251.

[20] Douglas MacKay, ND, *A Comparison of Synthetic Ethyl Ester Form Fish Oil vs. Natural Triglyceride Form* ("MacKay Publication"), http://www.healthwiseonline.com/pdf/stuart_tomc_nordic_naturals_tg_vs_ee.pdf; Bimbo, A, *Marin Oils*, AOCS Lipid Library, available at https://lipidlibrary.aocs.org/edible-oil-processing/marine-oils.

[21] *See* MacKay Publication; *see also Triglycerides vs. Ethyl Ester Forms of Fish Oil*, Science Based Health, https://www.sciencebasedhealth.com/Fish-Oil-EE-vs-TG-omega-3s-which-is-better-W119.aspx.

a condensate omega-3 ethyl ester solution. [22] The concentration of omega-3s in the solution depends on variables within the distillation process, but typically ranges from 50-70%.The constituent compounds are DHA Ethyl Esters and EPA Ethyl Esters—which are molecularly distinct from the precursor DHA and EPA triglyceride ("TAG") molecules. The diagram below shows the most common trans-esterification process beginning with crude fish oil and resulting in the formation of ethyl esters.[23]



53. The trans-esterification process allows manufacturers to do one of several things that yield significant financial benefits: (1) Increase the levels of EPA-EE and DHA-EE far in

[22] Molecular distillation is a type of short-path vacuum distillation, characterized by an extremely low vacuum pressure which is performed using a molecular still. This process is characterized by short term exposure of the distillate liquid to high temperatures in high vacuum in the distillation column and a small distance between the evaporator and the condenser. https://en.wikipedia.org/wiki/Molecular_distillation; *See also* Breivik, H., H. G.G., and B. Kristinsson, *Preparation of highly purified concentrates of eicosapentaenoic acid and docosahexaenoic acid*, JAOCS, 1997. 74(11): p. 1425-29; Breivik, H. *Concentrates. In: Long Chain Omega-3 Specialty Oils*, pp. 111-140, The Oily Press Bridgwater England (2007).

[23] Bimbo, A.P. *Processing of marine oils. In: Long Chain Omega-3 Specialty Oils*, pp. 77-109 (H. Breivik (ed.) The Oily Press Bridgwater England) (2007).

excess of the 18/12 limit of TAG EPA and TAG DHA in fish oil. Where the standard fish oil yields only 30% DHA/EPA by volume, trans-esterification allows manufacturers to obtain DHA-EE and EPA-EE that yields upwards of 70% by volume; (2) Alter the natural ratios of DHA/EPA (*i.e.*, 120 mg. / 180 mg. per 1000 mg.) to create DHA-EE / EPA-EE in any ratio the manufacturer desires; (3) Use low grade crude fish oil generated from fish offal—heads, viscera and other body parts discarded in preparing fish for consumption (*i.e.*, fish waste)—in lieu of a whole small oily fish (*e.g.*, sardine, anchovy, menhaden) that are traditionally caught and processed for the production of fish oil. In addition to being low quality, offal produces small volumes of oil compared to the whole fish because these edible species are primarily non-fatty fish.[24] For example, a study exploring the efficiency of extracting oil from the heads of two tuna species, found the crude oil yields are only between 1-2%, far less than the average yield from whole fish species that are caught specifically for rendering of fish oil.[25] Inconsistent and low yields, rancidity, and the fact that the raw materials consist of fish waste, renders the resulting crude fish oil unsuitable for human consumption and requires trans-esterification to create a consumable product.[26]

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[24] Bimbo, A. (2011). Marine oils; edible oil processing. AOCS Lipid Library, December 2016, available at http://lipidlibrary.aocs.org/OilsFats/content.cfm?ItemNumber=40332

[25] Kasmiran, B. 2018. Comparison and evaluation of the quality of fish oil and fishmeal extracted from the heads of Yellowfin tuna (Thunnus albacares) and Albacore tuna (Thinnus alalunga). Nations University Fisheries Training Programme, Iceland, available at http://www.unuftp.is/static/fellows/document/britney16prf.pdf.

[26] Alfio, V, et al., *From Fish Waste to Value: An Overview of the Sustainable Recovery of Omega-3 for Food Supplements*, Molecules. 2021 Feb; 26(4): 1002. Published online 2021 Feb 13. doi: 10.3390/molecules26041002 available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7918619/

54. At the end of the trans-esterification process, crude fish oil has been substantially transformed into Fatty Acid Ethyl Esters consisting of DHA-EE, EPA-EE and other OM3 fatty acid ethyl esters. At this point, the solution may be encapsulated and sold as a dietary supplement, or further concentrated, refined and sold as a drug.[27]

55. Ultimately, once trans-esterified, fish oil is substantially and irrevocably transformed into an Omega-3 fatty acid ethyl ester—a that cannot be found in any part of a fish. Calling it "fish oil," therefore, is fraudulent, deceptive and misleading.

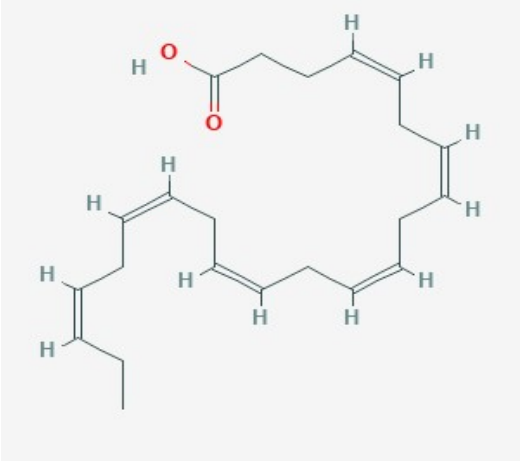
D. Omega-3 Fatty Acid Ethyl Esters Are Not Fish Oil

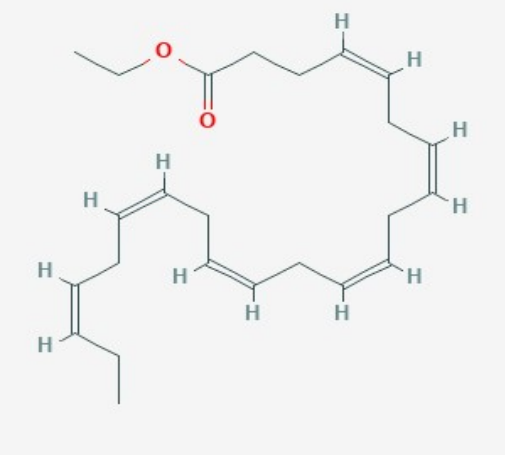
1. DHA & EPA Ethyl Esters are Different Molecules than DHA & EPA Found in Natural Fish Oil

56. The trans-esterification process substantially and irrevocably transforms the Omega-3s in fish oil from their natural triglyceride form into Omega-3 fatty acid ethyl esters. Critically, these substances, (fish oil and omega-3 fatty acid ethyl esters), are distinguishable on a molecular level such that it is impossible as a matter of law or logic for them to share a common or usual name. Indeed, they do not. Along with their molecular differences, they have different common or usual names which must be properly represented on labeling of any dietary supplement in which they are contained. To do otherwise is deceptive, misleading, fraudulent and illegal.

[27] *See e.g.*, Lovaza Prescribing information available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021654s023lbl.pdf.

	DHA[28]	DHA-EE[29]
Empirical Formulae	$C_{22}H_{32}O_2$	$C_{24}H_{36}O_2$
Molecular Weight	328.50 g/mol	356.55 g/mol
Synonyms	Docosahexaenoic acid Doconexent, Cervonic acid, Doconexento Doconexentum Doxonexent Docosahexaenoate	Docosahexaenoic acid ethyl ester Ethyl docosahexaenoate Cervonic acid ethyl ester
Molecular Structures		





	EPA[30]	EPA-EE[31]
Empirical Formulae	$C_{20}H_{30}O_2$	$C_{22}H_{34}O_2$

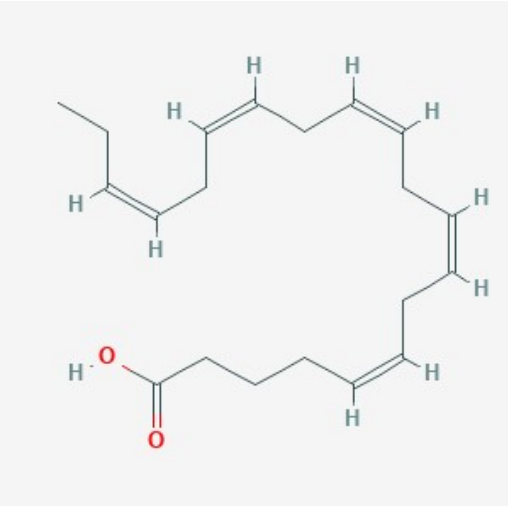
[28] *See* NIH, National Library of Medicine available at https://pubchem.ncbi.nlm.nih.gov/compound/445580

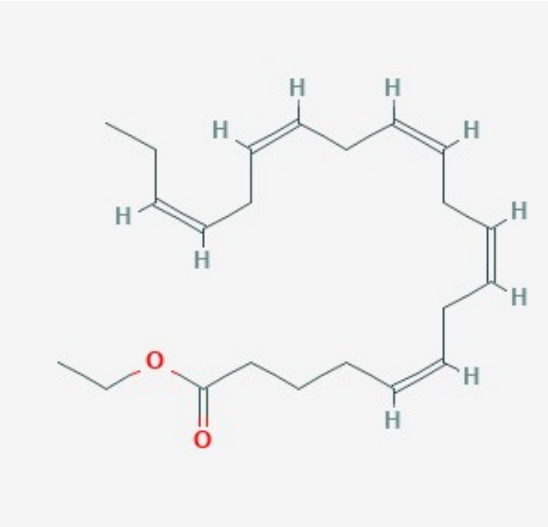
[29] *See* NIH, National Library of Medicine available at https://pubchem.ncbi.nlm.nih.gov/compound/9831416

[30] Pub Chem, available at https://pubchem.ncbi.nlm.nih.gov/compound/446284

[31] Pub Chem, available at https://pubchem.ncbi.nlm.nih.gov/compound/9831415

	EPA[30]	EPA-EE[31]
Molecular Weight	302.5 g/mol	330.51
Synonyms	Eicosapentaenoic acid Icosapent, 10417-94-4 Icosapento Icosapentum Timnodonic acid	Eicosapentaenoic acid ethyl ester Epadel Ethyl eicosapentaenoate Ethyl eicosapentaenoic acid Ethyl icosapentaenoate Ethyl icosapentate Ethyl-eicosapentaenoic acid Ethyl-EPA Icosapentaenoate icosapentate Icosapent ethyl Timnodonic acid ethyl ester
Molecular Structures		





57. As demonstrated above, these molecules are distinct in every regard. They have different molecular weights, chemical structures, physical properties and common/usual names.

2. <u>Monographs</u>

58. The United States Pharmacopeia ("USP") is one of the most comprehensive sources for medicine and dietary supplement standards in the world. The USP National

Formulary ("USP-NF") provides over 5000 reference standards for medicines and over 300 reference standards for dietary supplements. The standards are used to help ensure the quality of these products and their ingredients, and to protect the safety of patients.[32]

59. Among its quality standards, the USP-NF provides a series of monographs which articulate the quality expectations for "identity, strength, purity, and performance" of certain drugs and dietary supplements. *Id*. Included among the USP references for dietary substances are monographs for Docosahexaenoic Acid Ethyl Ester (500 mg.); Docosahexaenoic Acid (250 mg.); Eicosapentaenoic Acid (300 mg.); Eicosapentaenoic Acid Ethyl Ester; Fish Oil Omega-3 Acid Ethyl Esters Concentrate; Omega-3-Acid Ethyl Esters; and Fish Oil (1 g.).

60. Figure A below juxtaposes the mass spectra of the USP monograph for fish oil with that of NBI's 1400 mg Fish Oil.[33] As demonstrated below, fish oil is an amazingly complex natural product which consists of hundreds of constituent ingredients. In contrast, the NBI Product is a synthetic construct consisting primarily of DHA-EE and EPA-EE. Each peak represents a different molecule with a unique mass to charge ratio (m/z). From a macro perspective, the monographs undeniably demonstrate that these are distinct products. From a granular perspective, the monographs highlight the fact that, despite their representation to the contrary, the NBI Product contains no DHA or EPA, much less in the amounts claimed. Even worse, NBI sells at least two other Products which, like the 1400 mg Product, are also called "Fish Oil" (1000 mg and 1200 mg), but do indeed, as their mass spectrographs demonstrate,

[32] https://www.usp.org/about/public-policy/overview-of-monographs

[33] United States Pharmacopeia – National Formulary Catalog # 1270424, available at https://store.usp.org/OA_HTML/ibeCCtpItmDspRte.jsp?sitex=10020:22372:US&item=33515

consist of actual fish oil. A consumer looking at these products next to one another on a retail shelf would have no way of substantively differentiating them, much less cause to do so.

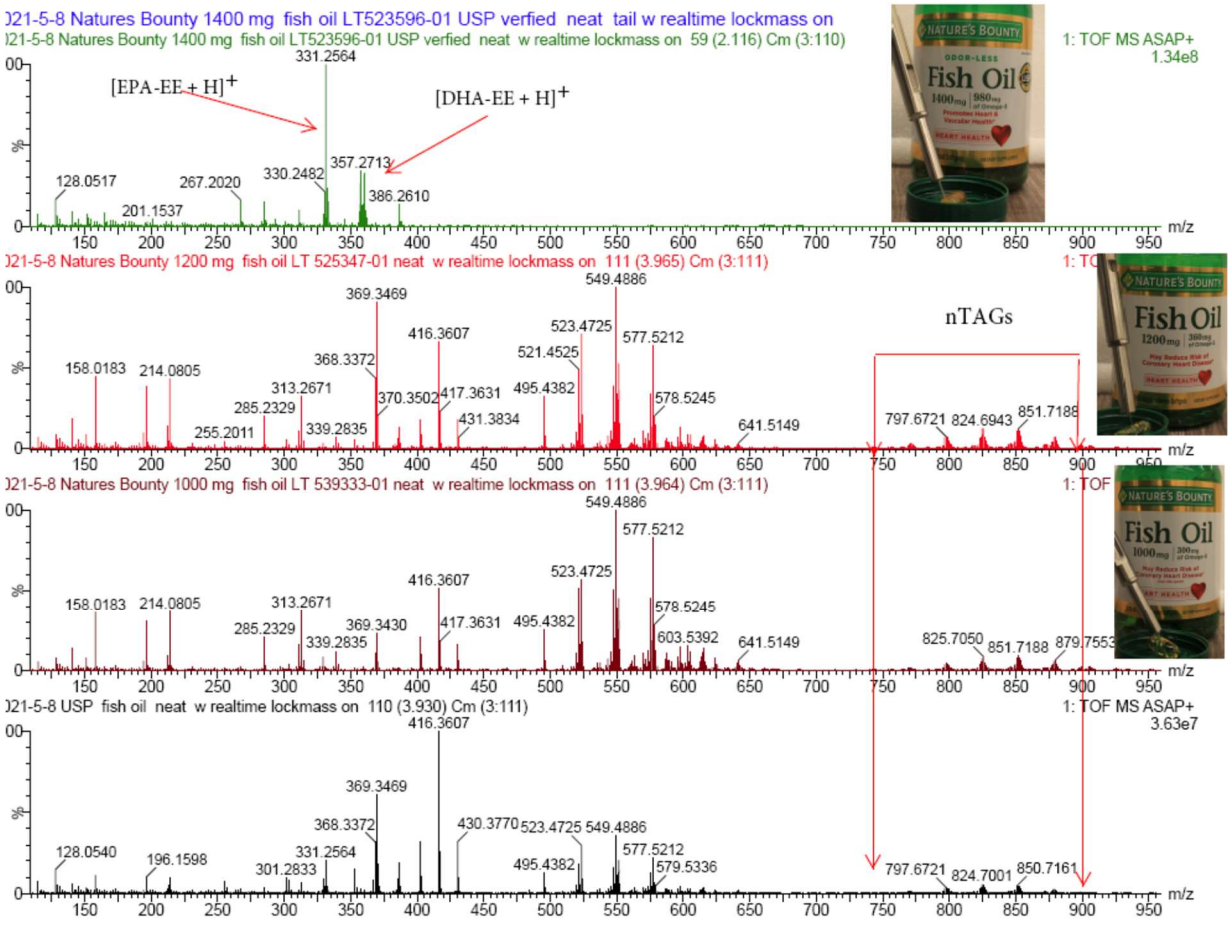


Figure A: Comparison of USP fish oil standard to NBI's 1400 mg, 1200 mg and 1000 mg Fish Oil.

61. In addition to the USP, numerous industry and scientific authorities independently confirm the differences between fish oil and omega-3 fatty acid ethyl esters.

62. Codex Alimentarius Commission ("Codex") was created in 1963 by two U.N. organizations, the Food and Agriculture Organization and the World Health Organization. Its main purpose is to protect the health of consumers and to ensure fair practices in international trade in food through the development of food standards, codes of practice, guidelines and other recommendations. Codex standards and guidelines are developed by committees, which are open to all member countries. Member countries review and provide comments on Codex standards and related texts at several stages in the development process. In the United States, public meetings are held to receive comments on Codex drafts and comments are invited from all interested parties. Although Codex standards and related texts are voluntary, they do provide a template for laws and are used by the World Trade Organization as an agreed benchmark in global trade disputes.[34]

63. FDA participates and exercises leadership in the Codex Alimentarius Commission. The objective of FDA's participation in Codex is to develop science-based international food safety, labeling, and other pertinent standards that provide consumer protection, labeling information, and prevention of economic fraud and deception that are consistent with U.S. regulations and laws.

[34] FDA, *Responses to Questions about Codex and Dietary Supplements*, available https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/responses-questions-about-codex-and-dietary-supplements#what (last visited April 13, 2021).

64. FDA uses procedures that promote consumer protection and transparency, as it works with the U.S. Codex Office to develop U.S. Delegation positions on matters before relevant Codex committees.[35]

65. In 2017, the Codex Alimentarius Committee adopted standards for fish oil. It was a long process that started in 2011, "involving many discussions on the finer details which was important to clarify as the purpose of this Standard is to protect consumer health and promote fair practices in the trade of fish oil."[36] Significantly, the Codex, like the USP, recognizes and draws a distinction between natural fish oil and trans-esterified products.[37]

66. Similarly, the Global Organization for EPA and DHA omega-3s ("GOED"), the largest and most significant trade group of the Omega-3 industry, also maintains a series of monographs which, like the USP and CODEX, differentiates between TAG, EE and rTG Omega-3s as well a series of particular fish oils (*e.g.*, Salmon, Tuna, Anchovy, etc.). It provides members "technical guidance on specific and recommended test methodologies and quality parameters for a number of EPA and/or DHA containing product classes currently covered under

[35] FDA, *FDA's Participation in Codex*, available at https://www.fda.gov/food/international-cooperation-food-safety/fdas-participation-codex (last visited April 13, 2021).

[36] IFFO, *CODEX Standard for Fish Oil*, available at https://www.iffo.net/codex-standard-fish-oil (last visited April 13, 2021).

[37] Section 2.2 defines "Fish oils" as those derived from one or more species of fish or shellfish.[37] In contrast, Section 2.6 defines "Concentrated fish oils ethyl esters" as those derived from fish oils described in Section 2.1 to 2.4 and are primarily composed of fatty acids ethyl esters. *See*, *Report of the U.S. Delegate, 25th Session, Codex Committee on Fats and Oils, United States Department of Agriculture*, available at https://www.usda.gov/sites/default/files/documents/delegates-report-02272017.pdf (last visited April 13, 2021).

the GOED Voluntary Monograph."[38] EPA/DHA-containing product classes currently covered by this GOED Voluntary Monograph: Refined EPA and/or DHA Omega-3 Oil Triglycerides, EPA and/or DHA Omega-3 Oil Ethyl Ester Concentrates, EPA and/or DHA Omega-3 Oil Triglyceride Concentrates, Tuna Oil, Salmon Oil and Anchovy Oil. Consistent with the USP and Codex, GOED's monographs confirm that fish oil is not synonymous with fatty acid ethyl esters and cannot be so named.

3. U.S. Customs and Border Protection

67. The U.S. Customs and Border Protection ("CBP") is one of the world's largest law enforcement organizations whose duties include the facilitation of lawful international trade.[39] Among other things, the CPB is responsible for the interpretation and enforcement of the Harmonized Tariff Schedule of the United States ("HTS") which is a hierarchical structure for describing all goods in trade for duty, quota, and statistical purposes.[40]

68. The CPB has issued more than 20,000 rulings related to the proper interpretation of products and where they may be classified under the HTS.

69. On several occasions the CPB considered the appropriate tariff classification for Omega-3 Acid Ethyl Esters. Consistently, the CPB recognized that trans-esterification

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[38] GOED Voluntary Monograph, Version 7.2, March 15, 2021 , available at https://goedomega3.com/goed-monograph (last visited April 13, 2021).

[39] *See*, U.S. Customs and Border Protection available at https://www.cbp.gov/about (last visited April 13, 2021).

[40] United States International Trade Commission, available at https://www.usitc.gov/harmonized_tariff_information (last visited April 13, 2021).

substantially transforms fish oil into a different product which results in a different tariff classification.

70. In 2011, the CPB tested and reviewed a product that was described as "a gelatin capsule containing 1000 milligrams of fish oil, said to be derived from anchovy, sardine, herring or other fish species." The CPB determined that the "fish oil" had been substantially transformed from its original fish oil source—"the crude fish oil has been refined and chemically modified by deodorizing, ethylating (conversion of triglycerides to ethyl esters), distillation, winterizing/cold filtrating, bleaching and drumming." Accordingly, while the petitioner sought to classify the trans esterified product under Section 1504.20.4000 of the HTS which pertains to "fish-liver oils and their fractions, whether or not refined, ***but not chemically modified***," the CPB concluded that "[b]ased on the manufacturing process of the fish oil, they will be classified elsewhere…. The applicable subheading for these products will be 2106.90.9998, HTSUS, which provides for food preparations not elsewhere specified or included…other…other…other. The duty rate will be 6.4 percent ad valorem." (emphasis added).[41]

[41] Customs Ruling, N171795, July 5, 2011, available at https://rulings.cbp.gov/search?term=N171795&collection=ALL&sortBy=RELEVANCE&pageSize=30&page=1; *See also,* HQ H295287 (June 18, 2020) available at https://rulings.cbp.gov/search?term=HQ%20H295287&collection=ALL&sortBy=RELEVANCE&pageSize=30&page=1 ("CBP has a long-standing position that in order to be classified in Chapter 15, HTSUS, as fats or oils, products must predominantly be composed of triglycerides. See Headquarters Ruling Letter ("HQ") H102457, dated September 8, 2010; HQ 963166, dated December 11, 2001; HQ 965396, dated July 23, 2002; HQ 964531, dated March 14, 2002; HQ 965699, dated September 25, 2002; New York Ruling Letter ("NY") N234974, dated November 19, 2012…. Accordingly, only products composed primarily of triglycerides are classifiable under heading 1515, HTSUS."); *See, also,* United States Pharmacopeia – National Formulary monograph catalog confirming different HTSUS as between fish oil and Omega-3 Fatty Acids.

71. Just as an apple cannot be called a pear, an omega-3 acid ethyl ester cannot be called fish oil. NBI's Product is a fatty acid ethyl ester. Labeling and selling it as fish oil is false, misleading, deceptive and unlawful.

SPECIFIC LABELING VIOLATIONS

72. The Federal Food, Drug & Cosmetic Act ("FDCA") broadly regulates the sale of food and beverages to the consuming public. 21 U.S.C § 301. It was promulgated in significant part to prevent consumer deception and was principally implemented through the creation of a uniform system of labeling on which consumers could rely to make informed purchasing decisions.

73. The FDCA prohibits the misbranding of any food. 21 U.S.C. § 331(b). Generally, a food is misbranded if, among other things, its labeling is false or misleading. 21 U.S.C. § 343.

74. The Nutrition Labeling and Education Act of 1990 amended the FDCA by requiring that most foods, including dietary supplements, bear nutrition labeling. Subsequently, the Dietary Supplement Health and Education Act of 1994 ("DSHEA") amended the Act, in part, by defining "dietary supplements," adding specific labeling requirements for dietary supplements, and providing for optional labeling statements.

75. Dietary supplements must bear labeling in accordance with applicable provisions of FDCA. NBI Product labels not only violate the clear mandates of the FDCA, but are independently false, misleading, and operate as a deception on the consuming public.

A. Fish Oil Is Not The Common Or Usual Name Of These Products

76. The principal display panel ("PDP") of the NBI Product describes the supplement as "Fish Oil."

77. Section 21 C.F.R. 101.3 states in relevant part:

> (a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity. (b) Such statement of identity shall be in terms of: (1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof, (2) The common or usual name of the food; or, in the absence thereof (3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

78. The statement of identity for a dietary supplement is the name that appears on the label of the dietary supplement. As a general matter, the statement of identity of a dietary supplement is the name specified by federal law or regulation, or, if no such name is specified, its common or usual name. If the dietary supplement has no common or usual name and its nature is not obvious, the statement of identity must be an appropriately descriptive term.[42]

79. As demonstrated in great detail herein, Fish Oil and Omega-3 Acid Ethyl Esters are not the same. They are different on a molecular level and have different common and usual names.

80. It is indisputable that the NBI Products were trans-esterified—a process that substantially transformed what was once natural fish oil containing OM3s in triglyceride form into a synthetic product consisting of fatty acid ethyl esters.

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[42] *See*, 21 U.S.C. 321(ff)(2)(C), 21 U.S.C. 343(s)(2)(B), 21 CFR §101.1 and 21 CFR §101.3; FDA Dietary Supplement Labeling Guide "FDA Labeling Guide") available at https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide-chapter-ii-identity-statement.

81. Consumers wishing to ingest Omega-3s have numerous choices. Principal among them, whether to take an Omega-3 supplement or consume a marine oil (*e.g.*, fish, krill, algae). Each product is molecularly different and has an array of qualities that differ from one another. These qualities differentiate the products in the marketplace and are material to consumers' purchasing decisions. NBI's failure to identify their Products by their common and usual name, obfuscated the most important information that is conveyed about a product—its name and contents. By failing to properly name its Products, NBI has deceived Plaintiffs and members of the class, depriving them of a consumer's most basic right—to make an informed purchasing decision.

1. <u>The Supplement Fact Section is False and Misleading</u>

82. Unfortunately for Plaintiffs and members of the class, the misrepresentation on the Principal Display Panel is further exacerbated by misrepresentations on the Supplement Facts panel on the back of the label. [43]

[43] NBI drops a "†" after the term "Omega-3 Fatty Acids" which when followed to the bottom of the back of the bottle admits it is an Ethyl Ester. As detailed above, Fish Oil does not contain ethyl esters and its Omega-3 content is in TAG form. *See*, https://www.naturesbounty.com/our-products/specialty/diet-supplements/odorless-fish-oil-1400-mg-30-rapid-release-softgels/.

Supplement Facts

Serving Size 1 Softgel

Amount Per Serving		%Daily Value
Calories	15	
Total Fat	1.5 g	2%**
Polyunsaturated Fat	1.5 g	***
Cholesterol	5 mg	2%
Fish Oil	1,400 mg (1.4 g)	***
provides 980 mg of Total Omega-3 Fatty Acids† comprising of:		***
EPA (Eicosapentaenoic Acid)	647 mg	***
DHA (Docosahexaenoic Acid)	253 mg	***
Other Omega-3 Fatty Acids		***

**Percent Daily Values are based on a 2,000 calorie diet.
***Daily Value not established.

83. Supplement manufacturers are generally required to disclose all ingredients contained in their products. 21 C.F.R. § 101.36. The obligation to describe those ingredients by their common or usual name applies with same force in the Supplement Fact section as it does on the principal display panel. As detailed above, the common or usual name of the contents of these Products is Omega-3 fatty acid ethyl esters AND NOT "Fish Oil." The Supplement Facts also erroneously claim the Product contains EPA and DHA, which it does not. As detailed above, this Product contains 0 mg of Eicosapentaenoic acid (EPA) and 0 mg Docosahexaenoic acid (DHA). Once trans-esterified, the EPA in fish was substantively modified into ethyl icosapentate (a/k/a Eicosapentaenoic acid ethyl ester) (EPA-EE) a molecule separate and distinct from EPA. Similarly, the Docosahexaenoic acid (DHA) in fish oil, once trans-esterified, was substantively modified into ethyl docosahexaenate (a/k/a Docosahexaenoic acid ethyl ester) (DHA-EE), a molecule sperate and distinct from DHA. Although both DHA-and DHA-EE may be listed by any number of synonyms, critically, none of their synonyms are shared. Failure to

properly identify EPA-EE and DHA-EE as constituent ingredients violates the mandates of the FDCA and independently renders the Products' Supplement Fact section false and misleading under state consumer protection laws.

84. As detailed above, trans-esterification substantially transformed "fish oil" into an Omega-3 acid ethyl ester. This transformation also affected all the individual components of the fish oil either by eliminating them entirely, or transforming them into fatty acid ethyl esters. Each of these omegas, although once triglycerides are now ethyl esters, different molecules with different common and usual names.

2. NBI Fails to List All the Ingredients in the Products

85. While the Product principally contains EPA-EE and DHA-EE, it also contains other omega-3s which NBI fails to identify and list in the Supplement Fact Sections in contravention of its obligations under the FDCA.

86. Section 21 C.F.R. § 101.36 applies specifically to the nutrition labeling of dietary supplements. It divides dietary ingredients into two categories—those that have a Reference Daily Intake (RDI), or a Daily Reference Value (DRV) as established in § 101.9(c) (referred to as "(b)(2)-dietary ingredients") and those that do not have an RDI/DRV (referred as "other ingredients"). 21 CFR §§ 101.36(b)(2) and (3).

87. Dietary ingredients for which no daily values have been established must be listed by their common or usual names when they are present in a dietary supplement. They must be identified as having no Daily Values by use of a symbol in the column for % Daily Value that refers to the footnote Daily Value Not Established. 21 CFR §§ 101.36(b)(2)(iii)(F) and (b)(3).

88. OM3s, in any form, do not have an RDI/DVR and therefore are considered other dietary ingredients. Their constituent components must be listed pursuant to 21 C.F.R. § 101.36(b)(3).

89. The Supplement Facts only account for 900 mg leaving 500 mg unaccounted for. NBI's failure to include these sub-components in the Supplement Fact Section further deprives consumers of material information relevant to making informed purchasing decisions. Failure to include this information operates as a fraud and deception on the consuming public and is violation of the law.

3. Other Labeling Misrepresentations

90. NBI proudly claims that the Product is USP certified. As detailed above, the USP is widely recognized as a leading authority on dietary supplement standards.[44]

91. Among its quality standards, the USP-NF provides a series of monographs which articulate the quality expectations for "identity, strength, purity, and performance" of certain drugs and dietary supplements. *Id*. Included among the USP references for dietary substances are monographs for Docosahexaenoic Acid Ethyl Ester (500 mg.); Docosahexaenoic Acid (250 mg.); Eicosapentaenoic Acid (300 mg.); Eicosapentaenoic Acid Ethyl Ester; Fish Oil Omega-3 Acid Ethyl Esters Concentrate; Omega-3-Acid Ethyl Esters; and Fish Oil (1 g.).

92. As clearly demonstrated in Figure A above, the mass spectrograph of the USP standard for fish oil is completely different than that of NBI's Product, rendering their claim that this Product is USP certified, false, deceptive and misleading.

[44] https://www.usp.org/about/public-policy/overview-of-monographs

93. In addition, the totality of the foregoing misrepresentations and violations, when read holistically, that is, in concert with each other, mislead Plaintiffs into believing that the Products have characteristics and traits that they do not have – namely, that the Product is fish oil, its Omega-3 content consists of DHA and EPA derived from fish oil, and that the veracity of these representations are independently verified by the USP.

ECONOMIC INJURY

94. Plaintiffs sought to buy Products that were lawfully labeled, marketed and sold.

95. Plaintiffs saw and relied on Defendants' misleading labeling of their Products.

96. Plaintiffs believed that the Products purchased contained real fish oil.

97. Plaintiffs believed that the Products were lawfully marketed and sold.

98. In reliance on the claims made by Defendants regarding the qualities of their Product, Plaintiffs paid for Products which they did not receive and/or for which they paid a price premium.

99. As a result of their reliance on Defendants' misrepresentations, Plaintiffs received a Product that lacked the promised principal ingredient and characteristics which they reasonably believed it contained.

100. Plaintiffs received a Product that was unlawfully marketed and sold.

101. Plaintiffs lost money and thereby suffered injury as they would not have purchased this Product and/or paid as much for it absent the misrepresentation.

102. Defendants know that the statement of identity and contents of a dietary supplement are material to a consumer's purchasing decision. By engaging in the false and

deceptive conduct alleged herein Defendants reaped, and continue to reap financial benefits in the form of sales and profits from their Product.

103. Plaintiffs would be willing to purchase NBI Products again in the future should they be able to rely on Defendants' labeling and marketing as non-deceptive.

CLASS ACTION ALLEGATIONS

104. Plaintiffs bring this action on behalf of themselves and on behalf of classes of all others similarly situated consumers defined as follows:

> **National**: All persons in the United States who purchased Class Products in the United States during the Class Period ("Nationwide Class").
>
> **New York:** All persons in New York who purchased the Class Products in New York during the Class Period ("New York Sub-Class").
>
> **California:** All persons in California who purchased the Class Products in California during the Class Period ("California Sub-Class").[45]
>
> **Class Period** is the maximum time allowable as determined by the statute of limitation periods accompanying each cause of action.

105. Plaintiffs bring these Classes pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(1), 23(b)(2), 23(b)(3) and 23(c)(4).

106. Excluded from the Classes are: (i) Defendants and their employees, principals, affiliated entities, legal representatives, successors and assigns; and (ii) the judges to whom this action is assigned.

[45] Collectively referred to as "Class or Classes."

107. Upon information and belief, there are tens of thousands of members of the Class. Therefore, individual joinder of all members of the Class would be impracticable.

108. There is a well-defined community of interest in the questions of law and fact affecting the parties represented in this action.

109. Common questions of law or fact exist as to all members of the Class. These questions predominate over the questions affecting only individual Class members. These common legal or factual questions include but are not limited to:

a. Whether Defendants marketed, packaged, or sold the Class Products to Plaintiffs and those similarly situated using false, misleading, or deceptive statements or representations;

b. Whether Defendants omitted or misrepresented material facts in connection with the sales of their Products;

c. Whether Defendants participated in and pursued the common course of conduct complained of herein;

d. Whether Defendants have been unjustly enriched as a result of their unlawful business practices;

e. Whether Defendants' actions violate the N.Y. Gen. Bus. Laws §§ 349, *et seq.*;

f. Whether Defendants' actions violate N.Y. Gen. Bus. Laws §§ 350 *et seq.*;

g. Whether Defendant's actions violate the Unfair Competition Law, Cal. Bus. & Prof. Code §§17200, *et seq*. (the "UCL");

h. Whether Defendant's actions violate the False Advertising Law, Cal.

Bus. & Prof. Code §§17500, *et seq*. (the "FAL");

i. Whether Defendant's actions violate the Consumers Legal Remedies Act, Cal. Civ. Code §§1750, *et seq*. (the "CLRA");

j. Whether Defendants' actions constitute breach of express warranty;

k. Whether Defendants should be enjoined from continuing the above-described practices;

l. Whether Plaintiffs and members of the Class are entitled to declaratory relief; and

m. Whether Defendants should be required to make restitution, disgorge profits, reimburse losses, and pay damages as a result of the above-described practices.

110. Plaintiff's claims are typical of the claims of the Class, in that Plaintiffs were consumers who purchased Defendants' Products. Plaintiffs are no different in any relevant respect from any other Class member who purchased the Product, and the relief sought is common to the Class.

111. Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the members of the Class they seek to represent, and they have retained counsel competent and experienced in conducting complex class action litigation. Plaintiffs and their counsel will adequately protect the interests of the Class.

112. A class action is superior to other available means for the fair and efficient adjudication of this dispute. The damages suffered by each individual Class member likely will be relatively small, especially given the cost of the Products at issue and the burden and expense of individual prosecution of the complex litigation necessitated by Defendants' conduct. Thus, it would be virtually impossible for members of the Class individually to effectively redress the

wrongs done to them. Moreover, even if members of the Class could afford individual actions, it would still not be preferable to class-wide litigation. Individualized actions present the potential for inconsistent or contradictory judgments. By contrast, a class action presents far fewer management difficulties and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

113. In the alternative, the Class may be certified because Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making appropriate preliminary and final equitable relief with respect to each Class.

114. The requirements for maintaining a class action pursuant to Rule 23(b)(2) are also met, as Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

FIRST CAUSE OF ACTION
Violation of Breach of Express Warranty
On Behalf of the New York and California Sub-Classes

115. Plaintiffs incorporate each and every allegation contained in the paragraphs above as if rewritten herein.

116. Plaintiffs' express warranty claims are based on violations of N.Y. CLS UCC § 2-313 and § 2-607 and Cal. Com. Code §2313. Defendants were afforded reasonable notice of this claim in advance of the filing of this complaint.

117. Defendants made express warranties to Plaintiffs and members of the New York and California Sub-Classes that the Products they purchased consisted of real fish oil in its

triglyceride form; that its principal constituent components were DHA and EPA (as opposed to DHA-EE and EPA-EE).

118. The express warranties made to Plaintiffs and members of the Sub-Classes appear on every Product label. This warranty regarding the nature of the Product marketed by Defendants specifically relates to the goods being purchased and became the basis of the bargain.

119. Plaintiffs and Sub-Class members purchased the Products in the belief that they conformed to the express warranties that were made on the Products' labels.

120. Defendants breached the express warranties made to Plaintiffs and members of the Class by failing to supply goods that conformed to the warranties it made. As a result, Plaintiffs and members of the Class suffered injury and deserve to be compensated for the damages they suffered.

121. Plaintiffs and the members of the Sub-Classes paid money for the Products. However, Plaintiffs and the members of the Sub-Classes did not obtain the full value of the advertised Products. If Plaintiffs and other members of the Sub-Classes had known of the true nature of the Products, they would not have purchased them or paid less for them. Accordingly, Plaintiffs and members of the Sub-Classes have suffered injury in fact and lost money or property as a result of Defendants' wrongful conduct.

122. Plaintiffs and Sub-Class members are therefore entitled to recover damages, punitive damages, equitable relief such as restitution and disgorgement of profits, and declaratory and injunctive relief.

SECOND CAUSE OF ACTION
Violation of N.Y. Gen. Bus. Law §§ 349, *et seq.*
On Behalf of the New York Sub-Class

123. Plaintiff Baines incorporates each and every allegation contained in the paragraphs above as if rewritten herein.

124. New York General Business Law Section 349 ("GBL § 349") declares unlawful "deceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state ..."

125. Defendants' labeling and marketing of the Product, as alleged herein, constitutes "deceptive" acts and practices within the meaning of GBL § 349.

126. Plaintiff Baines and New York Sub-Class Members have been injured inasmuch as they paid for and/or paid a premium for a Product that did not have the characteristics marketed, including that contrary to its label, was not fish oil and did not contain its claimed amount of DHA and EPA.

127. GBL § 349(h) provides in relevant part that "any person who has been injured by reason of any violation of [GBL § 349] may bring an action in his own name to enjoin such unlawful act or practice, an action to recover his actual damages or fifty dollars, whichever is greater, or both such actions. The court may, in its discretion, increase the award of damages to an amount not to exceed three times the actual damages up to one thousand dollars if the court finds the defendant willfully or knowingly violated this section. The court may award reasonable attorney's fees to a prevailing plaintiff."

128. In accordance with § 349(h), Plaintiff Baines seeks an order enjoining Defendants from continuing the unlawful deceptive acts and practices set forth above.

129. Absent a Court order enjoining the unlawful deceptive acts and practices, Defendants will continue their false and misleading marketing campaign and, in doing so, irreparably harm each member of the Class.

130. As a consequence of Defendants' deceptive acts and practices, Plaintiff Baines and other members of the New York Sub-Class suffered an ascertainable loss of monies.

By reason of the foregoing, Plaintiff and other members of the Class seek actual damages or statutory damages of $50 per violation, whichever is greater, as well as punitive damages. N.Y. GEN. BUS. LAW § 349(h).

THIRD CAUSE OF ACTION
Violation of N.Y. Gen. Bus. Law §§ 350, *et seq.*
On Behalf of the New York Sub-Class

131. Plaintiff Baines incorporates each and every allegation contained in the paragraphs above as if rewritten herein.

132. N.Y. Gen. Bus. Law § 350 declares false advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state to be unlawful. The term 'false advertising' means advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any employment opportunity if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual. 91. N.Y. Gen. Bus. Law § 350-a(l).

133. Defendants' labeling and advertisements contain untrue and materially misleading statements regarding the contents of the Supplement.

134. Plaintiff Baines and members of the New York Sub-Class have been injured inasmuch as they relied upon the labeling and advertising and paid a premium for a product that

did not conform to its representations. Accordingly, Plaintiff and New York Sub-Class members received less than what they bargained and/or for which they paid a premium.

135. Defendants' advertising and product labeling induced the Plaintiff and Class members to buy their Product.

136. Defendants knew, or by exercising reasonable care should have known, that their statements and representations as described in this Complaint were untrue and/or misleading.

137. Defendants made the material misrepresentations described in this Complaint on its Product labels.

138. As a result of Defendants' false or misleading labeling and advertising, Plaintiff and New York Sub-Class members are entitled to monetary damages, statutory damages, injunctive relief, restitution, disgorgement of all monies obtained by means of NBI's unlawful conduct, interest, and attorneys' fees and costs.

FOURTH CAUSE OF ACTION

Unlawful Business Practices
Violation of The Unfair Competition Law ("UCL")
Bus. & Prof. Code §§17200, *et seq*.
On Behalf of the California Sub-Class

139. Plaintiff Froning incorporates each and every allegation contained in the paragraphs above as if restated herein.

140. The UCL defines unfair business competition to include any "unlawful, unfair or fraudulent" act or practice, as well as any "unfair, deceptive, untrue or misleading" advertising. Cal. Bus. Prof. Code §17200.

141. A business act or practice is "unlawful" if it violates any established state or federal law.

142. Defendant's acts, omissions, misrepresentations, practices, and/or non-disclosures concerning the Products alleged herein, constitute "unlawful" business acts and practices in that

they violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301, et seq. and its implementing regulations, including, at least, the following sections:

a. 21 U.S.C. §343(a), which deems food misbranded when its labeling contains a statement that is false or misleading in any particular;

b. 21 C.F.R. §102.5(a)-(d), which prohibits the naming of foods so as to create an erroneous impression about the presence or absence of ingredient(s) or component(s) therein;

c. 21 U.S.C. §§331and 333, which prohibits the introduction of misbranded foods into interstate commerce.

d. 21 C.F.R. §101.3 and 21 C.F.R. §101.36 as described above, pertaining to, *inter alia,* use of common or usual names.

143. California has expressly adopted federal labeling requirements as its own pursuant to the Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code § 109875 et seq. (the "Sherman Law"), the Sherman Law, which provides that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state." Cal. Health & Safety Code § 110100.

144. This identical conduct serves as the sole factual basis of each cause of action brought by this Complaint, and Plaintiff does not seek to enforce any of the state law claims to impose any standard of conduct that exceeds that which would violate the FDCA.

145. Each of NBI's violations of federal law and regulations violates California's Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code § 109875 et seq. (the "Sherman Law"), including, but not limited to, the following sections:

146. Section 110100 (adopting all FDA regulations as state regulations);

147. Section 110290 ("In determining whether the labeling or advertisement of a food . . . is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account.");

148. Section 110390 ("It is unlawful for any person to disseminate any false advertisement of any food. . . . An advertisement is false if it is false or misleading in any particular.");

149. Section 110395 ("It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food . . . that is falsely advertised.");

150. Section 110398 ("It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.");

151. Section 110400 ("It is unlawful for any person to receive in commerce any food . . . that is falsely advertised or to deliver or proffer for delivery any such food . . . ."); and

152. Section 110660 ("Any food is misbranded if its labeling is false or misleading in any particular.").

153. Each of the challenged omissions, statements, and actions by NBI violates the FDCA, and the Sherman Law, and, consequently, violates the "unlawful" prong of the UCL.

154. Defendants' conduct is further "unlawful" because it violates California's False Advertising Law, Cal. Bus. & Prof. Code § 17500 et seq. (the "FAL"), and California's Consumers Legal Remedies Act, Cal. Civ. Code § 1750 et seq. (the "CLRA"), as discussed in the claims below.

155. By committing the unlawful acts and practices alleged above, Defendants have engaged, and continue to be engaged, in unlawful business practices within the meaning of California Business and Professions Code §§17200, *et seq.*

156. Through their unlawful acts and practices, Defendants have obtained, and continue to unfairly obtain, money from members of the California Sub-Class. As such, Plaintiff Froning requests that this Court cause Defendants to restore this money to Plaintiff and all members of the California Sub-Class, to disgorge the profits Defendants made on these transactions, and to enjoin Defendants from continuing to violate the Unfair Competition Law or violating it in the same fashion in the future. Otherwise, the California Sub-Class may be irreparably harmed and denied an effective and complete remedy if such an order is not granted.

FIFTH CAUSE OF ACTION

Unfair Business Practices
Violation of The Unfair Competition Law
Bus. & Prof. Code §§ 17200, *et seq*.
On Behalf of the California Sub-Class

157. Plaintiff Froning incorporates each and every allegation contained in the paragraphs above as if restated herein.

158. The UCL defines unfair business competition to include any "unlawful, unfair or fraudulent" act or practice, as well as any "unfair, deceptive, untrue or misleading" advertising. Cal. Bus. Prof. Code §17200.

159. A business act or practice is "unfair" under the Unfair Competition Law if the reasons, justifications and motives of the alleged wrongdoer are outweighed by the gravity of the harm to the alleged victims.

160. Defendants have violated, and continue to violate, the "unfair" prong of the UCL through their misleading description of the Product. The gravity of the harm to members of the California Sub-Class resulting from such unfair acts and practices outweighs any conceivable reasons, justifications, or motives of Defendants for engaging in such deceptive acts and practices. By committing the acts and practices alleged above, Defendants engaged, and continued to engage, in unfair business practices within the meaning of California Business and Professions Code §§17200, *et seq*.

161. Through their unfair acts and practices, Defendants obtained, and continued to unfairly obtain, money from members of the Class. As such, Plaintiff Froning has been injured and requests that this Court cause Defendants to restore this money to Plaintiff and the members of the California Sub-Class, to disgorge the profits Defendants made on their Products, and to enjoin Defendants from continuing to violate the Unfair Competition Law or violating it in the same fashion in the future. Otherwise, the California Sub-Class may be irreparably harmed and denied an effective and complete remedy if such an Order is not granted.

SIXTH CAUSE OF ACTION

Fraudulent Business Practices
Violation of The Unfair Competition Law
Bus. & Prof. Code §§ 17200, *et seq*.
On Behalf of the California Sub-Class

162. Plaintiff Froning incorporates each and every allegation contained in the paragraphs above as if restated herein.

163. The UCL defines unfair business competition to include any "unlawful, unfair or fraudulent" act or practice, as well as any "unfair, deceptive, untrue or misleading" advertising. Cal. Bus. & Prof. Code §17200.

164. A business act or practice is "fraudulent" under the Unfair Competition Law if it actually deceives or is likely to deceive members of the consuming public.

165. Defendants' acts and practices of mislabeling their Products in a manner to suggest they principally contained characterizing ingredients and/or properties that they do not.

166. As a result of the conduct described above, Defendants have been, and will continue to be, unjustly enriched at the expense of Plaintiff and members of the proposed Class. Specifically, Defendants have been unjustly enriched by the profits they have obtained from Plaintiff and members of the California Sub-Class from the purchases of its Products.

167. Through their fraudulent acts and practices, Defendants have improperly obtained, and continue to improperly obtain, money from members of the California Sub-Class. As such, Plaintiff requests that this Court cause Defendants to restore this money to Plaintiff and members of the California Sub-Class, to disgorge the profits Defendants have made, and to enjoin Defendants from continuing to violate the Unfair Competition Law or violating it in the same fashion in the future. Otherwise, the California Sub-Class may be irreparably harmed and denied an effective and complete remedy if such an Order is not granted.

SEVENTH CAUSE OF ACTION
False Advertising
Violation of California Bus. & Prof. Code §§ l7500, *et seq*.
On Behalf of the California Sub-Class

168. Plaintiff Froning incorporates each and every allegation contained in the paragraphs above as if restated herein.

169. Defendants use advertising and packaging to sell their Products. Defendants disseminate advertising regarding their Products which by their very nature are deceptive, untrue, or misleading within the meaning of California Business & Professions Code §§17500, *et seq.* because those advertising statements contained on the labels are misleading and likely to deceive, and continue to deceive, members of the putative Class and the general public.

170. In making and disseminating the statements alleged herein, Defendants knew or should have known that the statements were untrue or misleading, and acted in violation of California Business & Professions Code §§17500, *et seq*.

171. The misrepresentations and non-disclosures by Defendants of the material facts detailed above constitute false and misleading advertising and therefore constitute a violation of California Business & Professions Code §§17500, *et seq*.

172. Through their deceptive acts and practices, Defendants have improperly and illegally obtained money from Plaintiff and the members of the California Sub-Class. As such, Plaintiff Froning requests that this Court cause Defendants to restore this money to Plaintiff and the members of the California Sub-Class, and to enjoin Defendants from continuing to violate California Business & Professions Code §§17500, *et seq.*, as discussed above. Otherwise, Plaintiff and those similarly situated will continue to be harmed by Defendants' false and/or misleading advertising.

173. Pursuant to California Business & Professions Code §17535, Plaintiff seeks an Order of this Court ordering Defendants to fully disclose the true nature of their misrepresentations. Plaintiff additionally requests an Order: (1) requiring Defendants to disgorge

its ill-gotten gains, (2) award full restitution of all monies wrongfully acquired by Defendants and (3), interest and attorneys' fees. Plaintiff and the California Sub-Class may be irreparably harmed and denied an effective and complete remedy if such an Order is not granted.

EIGHTH CAUSE OF ACTION

Violation of the Consumers Legal Remedies Act
California Civil Code §§ 1750, *et seq*.
On Behalf of the California Sub-Class

174. Plaintiff Froning incorporates each and every allegation contained in the paragraphs above as if restated herein.

175. This cause of action is brought pursuant to the Consumers Legal Remedies Act, California Civil Code §§1750, *et seq*. (the "CLRA").

176. Plaintiff and each member of the proposed California Sub-Class are "consumers" within the meaning of Civil Code §1761(d).

177. The purchases of the Products by consumers constitute "transactions" within the meaning of Civil Code §1761(e) and the Products constitute "goods" within the meaning of Civil Code §1761(a).

178. Defendants have violated, and continue to violate, the CLRA in at least the following respects:

a. §1770(5) pertaining to misrepresentations regarding the characteristics of goods sold—specifying that misleading representations regarding ingredients violate the CLRA;

b. §1770(7) pertaining to misrepresentations regarding the standard, quality, or grade of goods sold; and

c. § 1770(9) pertaining to goods advertised with the intent not to provide what is advertised.

179. Defendants knew, or should have known, that the labeling of their Products violated consumer protection laws, and that these statements would be relied upon by Plaintiff and the members of the California Sub-Class.

180. The representations were made to Plaintiff and all members of the California Sub-Class. Plaintiff relied on the accuracy of the representations on Defendants' labels which formed a material basis for his decision to purchase the Products. Moreover, based on the very materiality of Defendants' misrepresentations uniformly made on or omitted from their Product labels, reliance may be presumed or inferred for all members of the Class.

181. Defendants carried out the scheme set forth in this Complaint willfully, wantonly, and with reckless disregard for the interests of Plaintiff and the California Sub-Class, and as a result, Plaintiff and the Class have suffered an ascertainable loss of money or property.

182. Plaintiff and the members of the California Sub-Class request that this Court enjoin Defendants from continuing to engage in the unlawful and deceptive methods, acts and practices alleged above, pursuant to California Civil Code §1780(a)(2). Unless Defendants are permanently enjoined from continuing to engage in such violations of the CLRA, future consumers of Defendants' Products will be damaged by their acts and practices in the same way as have Plaintiff and the members of the proposed Class.

183. Pursuant to Civil Code §1782, in conjunction with this filing, Plaintiff has provided notice to Defendants of the conduct described herein and that such conduct was in violation of particular provisions of Civil Code §1770. If Defendants refuse to take corrective within thirty days of receipt of the demand letter, Plaintiff will amend this complaint to add a claim for damages pursuant to Civil Code § 1780(a).

NINTH CAUSE OF ACTION
Restitution Based On Quasi-Contract/Unjust Enrichment
On Behalf of the Nationwide Class

184. Plaintiffs incorporate each and every allegation contained in the paragraphs above as if rewritten herein.

185. Defendants' conduct in enticing Plaintiffs and the Class to purchase their Products with false and misleading packaging is unlawful because the statements contained on the Defendants' Product labels are untrue.

186. Defendants took monies from Plaintiffs and the Class for these Products and have been unjustly enriched at the expense of Plaintiffs and the Class as result of their unlawful conduct alleged herein, thereby creating a quasi-contractual obligation on Defendants to restore these ill-gotten gains to Plaintiffs and the Class. It is against equity and good conscience to permit Defendants to retain the ill-gotten benefits received from Plaintiffs and Class members.

187. As a direct and proximate result of Defendants' unjust enrichment, Plaintiffs and the Class are entitled to restitution or restitutionary disgorgement in an amount to be proved at trial.

PRAYER FOR RELIEF

THEREFORE, Plaintiffs, on behalf of themselves and on behalf of the other members of the Classes and for the Counts so applicable on behalf of the general public request an award and relief as follows:

A. An order certifying that this action is properly brought and may be maintained as a class action, that Plaintiffs be appointed Class Representatives, and Plaintiffs' counsel be appointed Lead Counsel for the Class.

B. Restitution in such amount that Plaintiffs and all members of the Class paid to purchase Defendants' Product or restitutionary disgorgement of the profits Defendants obtained from those transactions, for Causes of Action for which they are available.

C. Compensatory damages for Causes of Action for which they are available.

D. Statutory penalties for Causes of Action for which they are available.

E. Punitive Damages for Causes of Action for which they are available.

F. A declaration and Order enjoining Defendants from marketing and labeling their Products deceptively, in violation of laws and regulations as specified in this Complaint.

G. An Order awarding Plaintiffs their costs of suit, including reasonable attorneys' fees and pre and post judgment interest.

H. An Order requiring an accounting for, and imposition of, a constructive trust upon all monies received by Defendants as a result of the unfair, misleading, fraudulent and unlawful conduct alleged herein.

I. Such other and further relief as may be deemed necessary or appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all causes of action or issues so triable.

Dated: January 6, 2022

Respectfully submitted,

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